5-29-14

Trenbolone was one of several chemicals tested at ORD, NHEERL, MED as a positive control representative of an endocrine mode of action used as part of the EDSP Tier 2 Test protocol development for the Endocrine Disrupter Screening Program run by the Office of Science Coordination and Policy (OSCP) of OCSPP. MED developed an amphibian EDSP Tier 2 test protocol, the Larval Amphibian Growth and Development Assay (LAGDA), and an EDSP Tier 2 fish test protocol, the Medaka Multi-generation Test (MMT). The test protocols were reviewed as part of an OSCP Science Advisory Panel (SAP) review of Proposed EDSP Tier 2 Ecotoxicity Tests held June 25-28, 2013. As part of the FACA review, the trenbolone data and summary of the findings is publically available on the OCSPP/OSCP Science Advisory Panel meetings public docket.
Below are the docket link and a listing of docket files pertaining to the MED work only. OSCP should be contacted for additional trenbolone data included in ISRs for other ecological species, e.g., Japanese quail.

SAP docket link

The Integrated Summary Reports (ISR) for both fish (MMT) and frog (LAGDA) can be found by going to EPA Science Advisory Panel website, under June 25-28, 2013 meeting on Proposed EDSP Tier 2 Ecotoxicity Tests, and looking under Meeting Materials: [filed under docket ID: EPA-HQ-OPP-2013-0182] The EPA site will have a link to the Regulations.gov site where the pdfs are downloadable.
http://www.epa.gov/scipoly/sap/meetings/2013/062513meeting.html#materials

LAGDA

Validation of the Larval Amphibian Growth and Development Assay (LAGDA): Integrated Summary Report (ISR)
EPA-HQ-OPP-2013-0182-0006.pdf

ERRATA on Statistical Analysis

Attachment (1) to FIFRA SAP ERRATA Memo on Statistical Analysis (FIFRA SAP ERRATA EPA-HQ-OPP-2013-0182-0071.pdf)

LAGDA Errata Validation of the Larval Amphibian Growth and Development Assay: Integrated Summary Report

LAGDA_Errata_Validation_of_the_Larval_Amphibian_Growth_and_Development_Assay_Integrated_Summary_Report.pdf

Other ORD, NHEERL, MED Cited in LAGDA ISR:

Olmstead AW, Kosian PA, Johnson R, Blackshear PE, Haselman J, Blanksma C, Korte JJ, Holcombe GW, Burgess E, Lindberg-Livingston A. 2012. Trenbolone causes mortality and altered sexual differentiation in *Xenopus tropicalis* during larval development. Environmental Toxicology and Chemistry 31(10):2391-2398.

MMT

Validation of the Medaka Multigeneration Test (MMT): Integrated Summary Report (ISR):
EPA-HQ-OPP-2013-0182-0005.pdf

ERRATA on Statistical Analysis

Attachment (2) to FIFRA SAP ERRATA Memo on Statistical Analysis (FIFRA SAP ERRATA EPA-HQ-OPP-2013-0182-0071.pdf)

Errata MMT (2) Validation of the Medaka Multigeneration Test: Integrated Summary Report

Errata_MMT_(2)_Validation_of_the_Medaka_Multigeneration_Test_Integrated_Summary_Report.pdf

Additional ISR Appendices mentioning Trenbolone data:

Appendix F: Pathology Guidance
EPA-HQ-OPP-2013-0182-0031.pdf

Appendix G: Statistical Procedures
EPA-HQ-OPP-2013-0182-0032.pdf

Appendix H: Test data, graphs, etc
EPA-HQ-OPP-2013-0182-0033.pdf

Appendix I: Power Analysis
EPA-HQ-OPP-2013-0182-0034.pdf

Non-MED but NHEERL references cited in MMT Integrated Summary Report (ISR):

Cripe, G.M., Hemmer, B.L., Raimondo, S., Goodman, L.R., Kulaw, D.H., 2010. EXPOSURE OF THREE GENERATIONS OF THE ESTUARINE SHEEPSHEAD MINNOW (CYPRINODON VARIEGATUS) TO THE ANDROGEN, 17 beta-TRENBOLONE: EFFECTS ON SURVIVAL, DEVELOPMENT, AND REPRODUCTION. Environmental Toxicology and Chemistry 29, 2079-2087.

Wilson, V.S., Lambright, C., Ostby, J., Gray, L.E., Jr., 2002. *In Vitro* and *in Vivo* Effects of 17beta- Trenbolone: A Feedlot Effluent Contaminant. Toxicol. Sci. 70, 202-211.